# Genmab Announces Data From Multiple Clinical Trials Showing Treatment with Fixed-Duration Epcoritamab Led to Remissions in First-Line Diffuse Large B-Cell Lymphoma (DLBCL) and Follicular Lymphoma (FL)

## Media Release

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- **New two- and three-year EPCORE® NHL-2 follow-up data evaluating epcoritamab in combination with standard of care regimens demonstrate remission in patients with DLBCL and FL**
- **Latest EPCORE DLBCL-3 trial results show encouraging overall response and complete response rates for epcoritamab monotherapy in newly-diagnosed, elderly patients with DLBCL**
- **Data presented at the 67th Annual Meeting and Exposition of the American Society of Hematology (ASH) reinforce the potential utility of epcoritamab in earlier lines of therapy with a fixed treatment duration**

**Genmab A/S (Nasdaq: GMAB) today announced updated results from two ongoing clinical trials evaluating the efficacy and safety of epcoritamab-bysp, a T-cell engaging antibody administered subcutaneously, as a monotherapy and in combination with other standard of care treatments in adult patients with diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL).** Results from two arms of the EPCORE® NHL-2 trial, evaluating first-line, fixed-treatment duration epcoritamab in combination with chemotherapies, demonstrated overall response rates (ORR) of 93% (Arm 8) and 98% (Arm 1) in patients with newly-diagnosed DLBCL, while a third arm (Arm 3) demonstrated a three-year overall survival (OS) rate of 96% in patients with FL following first-line combination treatment.

In EPCORE DLBCL-3, the ORR was 73% in elderly patients with DLBCL treated with first-line, fixed-duration epcoritamab monotherapy who were unable to receive standard anthracycline-based chemotherapy. The study also showed that 54% of patients were progression free and 65% were alive at one year. The results from both studies were presented today in two oral presentations (abstracts 63 and 64) and two poster presentations (abstracts 1955 and 5357) at the 67th Annual Meeting and Exposition of the American Society of Hematology (ASH), in Orlando, Florida.

**EPCORE® NHL-2, Arm 8 Results**
Two-year follow up from Arm 8 of the EPCORE NHL-2 trial (abstract 64) showed fixed-duration epcoritamab plus rituximab plus dose-attenuated cyclophosphamide, doxorubicin, vincristine, and prednisone (R-mini-CHOP) demonstrated an ORR of 93% and complete response (CR) rate of 86% in elderly patients with newly diagnosed DLBCL ineligible for full-dose R-CHOP due to age or comorbidities (n=28). Responses were maintained at two years for an estimated 79% of all responders. Additionally, 20 out of 22 patients who completed the eight cycles of treatment had a CR at the end of treatment and 90% of them remained in CR nearly two years later. Minimal residual disease (MRD) negativity was reported in 20 out of 21 evaluable patients, including clinically relevant sub-groups; this was achieved in 16 patients by the start of cycle 3, and 12 maintained this status through the start of cycle 6.

Treatment-emergent adverse events (TEAEs) were consistent with previous studies evaluating epcoritamab and included Grade ≥3 infection in 32% (n=9) of patients, occurring within the first 6 cycles of treatment in the majority (7/9) of these patients. TEAEs led to epcoritamab discontinuation in 11% (n=3) of patients, including Grade 2 rhinitis, Grade 2 cytokine release syndrome (CRS), and Grade 5 confusional state and cytomegalovirus infection reactivation in a 90-year-old patient with a recent acute cerebrovascular accident.

“Despite an older population of newly diagnosed diffuse large B-cell lymphoma, the outcomes observed in Arm 8 of the EPCORE NHL-2 evaluating fixed-duration epcoritamab plus R-mini-CHOP are encouraging,”

said Chan Cheah, M.D., Sir Charles Gairdner Hospital and the University of Western Australia, Nedlands, Australia. “These results, along with those from other arms of the trial, support the potential for combinations of epcoritamab with standard of care treatment across a range of disease settings and patient populations.”

**EPCORE® NHL-2; Arm 1 Results**
In Arm 1 (abstract 1955), treatment with fixed-duration epcoritamab plus R-CHOP resulted in durable remissions lasting more than three years in most patients with newly diagnosed DLBCL and high International Prognostic Index (IPI) scores, an indicator of poor prognosis (n=47). After a median follow up of 44.2 months (95% CI, 38.9-44.4), the ORR was 98% and the CR rate was 85%. An estimated 74% of CRs were ongoing at three years. High CR rates were observed regardless of IPI score (IPI 3, 86% vs IPI 4-5, 83%). At three years, an estimated 69% of patients remained progression free and 83% were alive; survival outcomes were consistent regardless of IPI score (3 vs 4–5). Efficacy outcomes were also similar across subgroups based on age (≤60 vs >60 years), tumor size (<10 vs ≥10 cm), or cell of origin (germinal center B cell [GCB] vs non-GCB). By cycle 3, 86% of MRD evaluable patients were MRD negative and the reduction of circulating tumor DNA (ctDNA) levels was sustained through post-treatment follow-up in most patients with CR.

Serious and Grade ≥3 infections primarily occurred in the first six months of treatment, then rates decreased. Safety was consistent with prior reports. No new serious infections were reported in the post-treatment period. No new Grade 5 adverse events (AEs) were reported.

**EPCORE® NHL-2; Arm 3 Results**
Data from Arm 3 (abstract 5357) showed that treatment with fixed-duration epcoritamab plus bendamustine and rituximab (BR) for the first-line treatment of FL resulted in deep and durable responses at a median follow-up of 41.3 months. Three-year estimates for duration of response (DOR), duration of CR (DOCR), progression-free survival (PFS) and OS were 87%, 87%, 83% and 96%, respectively. PFS was consistently high overall and in both low- and high-risk subgroups. These results underscore the potential for long-term efficacy of this first-line treatment combination in FL.

No new safety signals were reported after the data cutoff/additional 11 months of follow up. Grade ≥3 TEAEs and serious TEAEs, including neutropenia and infection, primarily occurred in the first 24 weeks of treatment, coinciding with the epcoritamab plus BR treatment period, and rates improved over time during the epcoritamab monotherapy treatment period. Since the prior data cutoff, three patients experienced new COVID-19 infection events (Grade 1-2). There was a sustained reduction in peripheral CD4+ T cells, whereas peripheral CD8+ T cells expanded after the first full dose, resulting in a reduced CD4:CD8 ratio.

“The ongoing epcoritamab development program continues to generate positive data supporting its potential as a core therapy alone and in combination across a range of B-cell malignancies, both as an initial treatment and in later lines of therapy,” said Dr. Judith Klimovsky, Executive Vice President and Chief Development Officer of Genmab. “We look forward to progressing our research as we seek to advance treatment in these areas of critical need.”

**EPCORE® DLBCL-3 Trial Results**
Separately, new results from the ongoing Phase 2 EPCORE DLBCL-3 trial (abstract 63), for fixed-duration epcoritamab monotherapy in newly diagnosed elderly patients with DLBCL and comorbidities, were also presented.

An ORR of 73% was observed (n=60 response evaluable patients), and 62% of patients achieved a CR. Median time to response was 1.5 months, and median time to CR was 2.1 months; eight patients with a

partial response or stable disease at first assessment achieved a CR at subsequent assessments. Median duration of response (mDOR) and median duration of CR (mDOCR) were not reached (NR). An estimated 70% of all responses and 78% of CRs were ongoing at one year. In the overall population (N=66), median PFS was 13.0 months (95% CI, 5.4–NR) and median OS was NR (95% CI, 13.0–NR). An estimated 54% of patients were progression free, and 65% were alive at one year. Additionally, MRD negativity in responders was also reached early and was maintained, with most becoming MRD negative by the third treatment cycle and sustained through post-treatment follow-up.

Safety was consistent with previous reports of epcoritamab monotherapy in this population. TEAEs occurred in 94% of patients, with CRS (71%), diarrhea (23%), and fatigue (23%) being most frequent (≥20%). CRS events were primarily low Grade (Grade 1: 38%; Grade 2: 29%; Grade 3: 5%), with most (92%) occurring in cycle 1; 98% of cases resolved by data cutoff. ICANS occurred in 18% of patients (Grade 1: 8%; Grade 2: 8%; Grade 3: 3%); 11/12 cases resolved by data cutoff. Neutropenia was reported in 16% of patients, 68% of patients had an infection of any Grade, and 23% had a Grade ≥3 infection. Two additional Grade 5 TEAEs (pneumonia, death) occurred since the previous disclosure.

“Elderly patients who are living with diffuse large B-cell lymphoma, particularly those with comorbidities, often are not able to tolerate standard treatment, creating a tremendous need for effective chemotherapy-free options,” said Umberto Vitolo, M.D.,Candiolo Cancer Institute in Turin, Italy. “The study showed that treatment with fixed-duration epcoritamab as a monotherapy demonstrated encouraging results in this population that typically has poor outcomes.”

The safety and efficacy of epcoritamab have not been established for these investigational uses.

**About Diffuse Large B-Cell Lymphoma (DLBCL)**
DLBCL is the most common type of non-Hodgkin lymphoma (NHL) worldwide, accounting for approximately 25-30 percent of all NHL cases.[i] In the U.S., there are approximately 25,000 new cases of DLBCL diagnosed each year.[ii] DLBCL can arise in lymph nodes as well as in organs outside of the lymphatic system, occurs more commonly in the elderly and is slightly more prevalent in men.[iii,iv] DLBCL is a fast-growing type of NHL, a cancer that develops in the lymphatic system and affects B-cell lymphocytes, a type of white blood cell. For many people living with DLBCL, their cancer either relapses, which means it may return after treatment, or become refractory, meaning it does not respond to treatment. Although new therapies have become available, treatment management can remain a challenge.

**About Follicular Lymphoma (FL)**
FL is typically an indolent (or slow-growing) form of non-Hodgkin lymphoma (NHL) that arises from B-lymphocytes and is the second most common form of NHL accounting for 20-30 percent of all cases.[v] About 15,000 people develop FL each year in the U.S.[vi] and it is considered incurable with current standard of care therapies.[vii] Patients often relapse and, with each relapse the remission and time to next treatment is shorter.[viii] Over time, transformation to diffuse large B-cell lymphoma (DLBCL), an aggressive form of NHL associated with poor survival outcomes, can occur in more than 25 percent of FL patients.[ix]

**About the EPCORE® NHL-2 Trial**
EPCORE NHL-2 is a Phase 1b/2 open-label interventional trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics/biomarkers, immunogenicity, and preliminary efficacy of epcoritamab as a monotherapy and in combination with other standard of care agents in patients with B-cell non-Hodgkin lymphoma (B-NHL). The trial consists of two parts: Part 1 (Dose Escalation) and Part 2 (Dose Expansion). The primary objective of Part 1 is safety, and the primary goal of Part 2 is preliminary

efficacy. The primary endpoint was overall response rate (ORR) based on best overall response per Lugano criteria. MRD negativity was assessed as a secondary endpoint.

More information on this trial can be found at https://www.clinicaltrials.gov/ (NCT: 04663347).

**About the EPCORE® DLBCL-3 Trial**
EPCORE DLBCL-3 is an open-label, randomized, global, Phase 2 trial to evaluate the efficacy and safety of epcoritamab as monotherapy or in combination with lenalidomide as first-line therapy for anthracycline-ineligible subjects with diffuse large B-cell lymphoma (DLBCL). This is a 2-stage trial. In Stage 1, eligible patients will be randomized to either epcoritamab monotherapy or epcoritamab plus lenalidomide. In Stage 2, additional patients may be enrolled at the treatment regimen selected for expansion. Each treatment cycle is 28 days. Patients will receive a maximum of 12 cycles (up to 1 year) of treatment. The primary objective is to evaluate the clinical efficacy of epcoritamab monotherapy or epcoritamab and lenalidomide. The primary endpoint is to achieve a complete response rate determined by Lugano criteria. Additional secondary endpoints include overall response rate, duration of response, duration of complete response, rate of minimal residual disease negativity, progression-free survival and overall survival.

More information on this trial can be found at https://www.clinicaltrials.gov/ (NCT:05660967).

**About Epcoritamab**
Epcoritamab is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody® technology and administered subcutaneously. Genmab's DuoBody-CD3 technology is designed to direct cytotoxic T cells selectively to elicit an immune response toward target cell types. Epcoritamab is designed to simultaneously bind to CD3 on T cells and CD20 on B cells and induces T-cell-mediated killing of CD20+ cells.[x]

Epcoritamab (approved under the brand name EPKINLY® in the U.S. and Japan, and TEPKINLY® in the EU) has received regulatory approval in certain lymphoma indications in several territories. Where approved, epcoritamab is a readily accessible therapy. Epcoritamab is being co-developed by Genmab and AbbVie as part of the companies' oncology collaboration. The companies will share commercial responsibilities in the U.S. and Japan, with AbbVie responsible for further global commercialization. Both companies will pursue additional international regulatory approvals for the investigational R/R FL indication and additional approvals for the R/R DLBCL indication.

Genmab and AbbVie continue to evaluate the use of epcoritamab as a monotherapy, and in combination, across lines of therapy in a range of hematologic malignancies. This includes four ongoing Phase 3, open-label, randomized trials, among them a trial evaluating epcoritamab as a monotherapy in patients with R/R DLBCL compared to investigators choice chemotherapy (NCT04628494), a trial evaluating epcoritamab in combination with R-CHOP in adult patients with newly diagnosed DLBCL (NCT05578976), a trial evaluating epcoritamab in combination with $R^2$ compared to chemoimmunotherapy in patients with previously untreated FL (NCT06191744), and a trial evaluating epcoritamab in combination with lenalidomide compared to chemotherapy infusion in patients with R/R DLBCL (NCT06508658). The safety and efficacy of epcoritamab has not been established for these investigational uses. Please visit www.clinicaltrials.gov for more information.

**About Genmab**
Genmab is an international biotechnology company with a core purpose of guiding its unstoppable team to strive toward improving the lives of patients with innovative and differentiated antibody therapeutics. For 25 years, its passionate, innovative and collaborative team has invented next-generation antibody

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technology platforms and leveraged translational, quantitative and data sciences, resulting in a proprietary pipeline including bispecific T-cell engagers, antibody-drug conjugates, next-generation immune checkpoint modulators and effector function-enhanced antibodies. By 2030, Genmab's vision is to transform the lives of people with cancer and other serious diseases with knock-your-socks-off (KYSO) antibody medicines.®

Established in 1999, Genmab is headquartered in Copenhagen, Denmark, with international presence across North America, Europe and Asia Pacific. For more information, please visit Genmab.com and follow us on LinkedIn and X.

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